



NOV - 3 2004

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James L. Wilmer, Ph.D.
Director, Scientific Affairs
Market America, Inc.
1302 Pleasant Ridge Road
Greensboro, North Carolina 27409

Dear Dr. Wilmer:

This is in response to your letter of October 20, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter states that the product **LipiTrim Ultra** will use the claims "[M]aintain cholesterol levels within a healthy range," "[I]nhibit the production of excessive cholesterol by your body to safely maintain healthy cholesterol levels," "[P]romotes healthy cholesterol levels...inhibit an enzyme that makes cholesterol in the liver," and "Advanced Cholesterol Support Formula."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. Therefore, because the claims you are making for this product represent that the product is intended to affect blood cholesterol but do not also include a statement about it being intended to affect blood cholesterol that is already in the normal ranges, they are implied disease claims.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely yours,

for Robert J. Moore

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Atlanta District Office, Office of Compliance, HFR-SE140

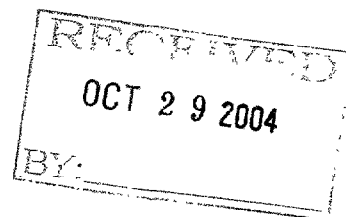
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October 20, 2004

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S. W.
Washington, D. C. 20204



Dear Sir/Madam:

I have enclosed notification forms that are intended to comply with Section 6 of the Dietary Supplement Health and Education Act of 1994 and Rule 21 C.F.R. §101.93. One dietary supplement called *Lipitrim® Ultra* is discussed. I have listed the structure-function statements found on the product label and associated support literature, and have identified the product ingredients that are the subject of the statements.

Thank you.

Sincerely,

A handwritten signature in cursive script that reads "James L. Wilmer".

James L. Wilmer, Ph. D.
Director, Scientific Affairs

Enclosures: 1 original and 2 copies

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**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR §101.93**

This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **1302 Pleasant Ridge Road, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **LipiTrim® Ultra**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "LipiTrim Ultra provides a powerful formulation to help maintain cholesterol levels within a healthy range."—Booklet

Statement 2: "It uses a combination of natural ingredients that help inhibit the production of excessive cholesterol by your body to safely maintain healthy cholesterol levels."—Booklet

Statement 3: "LipiTrim Ultra Advanced Cholesterol Support Formula promotes healthy cholesterol levels through the use of two potent ingredients, tocotrienols and policosanols, both found to inhibit an enzyme that makes cholesterol in the liver."
—Booklet

Statement 4: "Lipitrim Ultra is designed to help you maintain proper heart health."
—Website

Statement 5: "Advanced Cholesterol Support Formula"—Bottle Label

Statement 6: "Heart Health - Cardiovascular Maintenance"—Bottle Label

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

Statement Number(s)	Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement
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1.-6.	LipiTrim Ultra is composed of the following ingredients: tocotrienol complex (from 167 mg NuTriene™ 30% Tocotrienol Oil), policosanols (from 11.2 mg
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MarcosanTM 90% Policosanol complex); other ingredients include: soybean oil, gelatin, glycerin, soy lecithin, beeswax, chlorophyll and titanium dioxide.

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number(s)</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.-6.	LipiTrim [®] Ultra	Bottle Label and Booklet

I, James L. Wilmer, am authorized to certify this Notification on behalf of Market America, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that Market America, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: October 20, 2004

By: James L. Wilmer

James L. Wilmer, Ph. D.
Director, Scientific Affairs
Market America, Inc.